DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 15 2007

Re: Lunesta
Docket No.: 2005E-0255

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,444,673, filed by Sepracor, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lunesta (eszopiclone), the human drug product claimed by the patent.

The total length of the regulatory review period for Lunesta (eszopiclone) is 1,941 days. Of this time, 1,256 days occurred during the testing phase and 685 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 25, 1999.

   The applicant claims August 21, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 25, 1999, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: January 31, 2003.

   The applicant claims January 30, 2003, as the date the new drug application (NDA) for Lunesta (NDA 21-476) was initially submitted. However, FDA records indicate that NDA 21-476 was submitted on January 31, 2003.

3. The date the application was approved: December 15, 2004.

   FDA has verified the applicant's claim that NDA 21-476 was approved on December 15, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Philip E. Hansen
Heslin Rothenberg Farley & Mesiti, P.C.
5 Columbia Circle
Albany, NY 12203-5160